10/019134
JC13 Rec'd PCT/PTO 20 DEC 2001
Case CL/V-31010A/CVE 64

3/prts

## UV illumination device

The invention relates to a method and device for crosslinking a biocompatible, polymerisable material in order to produce an ophthalmic moulding, especially an ophthalmic lens, particularly a contact lens.

Contact lenses, which are to be manufactured economically in large unit numbers, are preferably manufactured by the so-called mould or full-mould process. In these processes, the lenses are manufactured into their final shape between two mould halves, so that there is no need to subsequently finish the surfaces of the lenses, nor to finish the edges. Mould processes are described for example in PCT patent application no. WO/87/04390 or in EP-A 0 367.513.

The contact lenses produced in this manner are moulded parts having little mechanical stability and a water content of more than 60 % by weight. After manufacture, the lens is inspected, then packed and subjected to heat sterilisation at 121°C in an autoclave.

In these known mould processes, the geometry of the contact lenses to be manufactured is defined by the mould cavity. The edge of the contact lens is likewise formed by the mould which normally consists of two mould halves. The geometry of the edge is defined by the contour of the two mould halves in the area in which they make contact.

To manufacture a contact lens, first of all a certain amount of a flowable starting material is placed in the female mould half. Afterwards, the mould is closed by placing the male mould half thereon. Normally, a surplus of starting material is used, so that, when the mould is closed, the excess amount is expelled out into an overflow area adjacent to the mould cavity. The subsequent polymerisation or crosslinking of the starting material takes place by radiation with UV light, or by heat action, or by another non-thermal method.

In US-A-5,508,317, a new contact lens material is described, which represents an important improvement in the chemistry of polymerisable starting materials for the manufacture of contact lenses. The patent discloses a water-soluble composition of a prepolymer, which is filled into the mould cavity and then crosslinked photochemically. Since the prepolymer has several crosslinkable groups, the crosslinking is of high quality, so that a finished lens of

optical quality can be produced within a few seconds, without the necessity for subsequent extraction or finishing steps. Owing to the improved chemistry of the starting material as illustrated in the patent, contact lenses can be produced at considerably lower cost, so that in this way it is possible to produce disposable lenses that are used only once.

EP-A-0 637 490 describes a process by means of which a further improvement may be obtained in the preparation process of contact lenses with the prepolymer described in US-A-5,508,317. Here, the material is filled into a mould comprising two halves, whereby the two mould halves do not touch, but a thin circular gap is located between them. The gap is linked to the mould cavity, so that surplus lens material can flow away into the gap. Instead of the polypropylene moulds that may be used only once, reusable quartz/glass moulds may be used. Because of the water-soluble basic chemistry, after a lens has been produced, the uncrosslinked prepolymer and other residues can be removed from the moulds rapidly and effectively with water, and the moulds dried in the air. In this way, high precision of the lens shaping may also be achieved. Crosslinking of the prepolymer takes place by radiation especially with UV light, whereby radiation is restricted to the mould cavity by a chromium screen. In this way, only the material in the mould cavity is crosslinked, so that there is high reproducibility of the edges of the lens without closing the two polypropylene mould halves. The uncrosslinked shaded-off prepolymer solution can be easily washed away from the shaped, crosslinked lens with water.

However, during radiation with conventional UV lamps, there are frequently problems concerning homogeneity of radiation, especially when using glass casting moulds. Owing to the uneven illumination of the mould cavity, the moulding may have a varying degree of crosslinking, which has a negative effect on the stability of the moulding. The edges in particular are frequently insufficiently polymerised, so that the borders of the moulding are not clearly defined.

The invention is concerned with the problem of further improving the crosslinking process for ophthalmic mouldings consisting of biocompatible polymerisable materials, especially for contact lenses, in order to ensure constant quality of the mouldings.

The invention solves this problem with the features indicated in claim 1. As far as further essential embodiments of the process according to the invention and of the device according to the invention are concerned, reference is made to the dependent claims.

By coupling the UV light into the mould cavity using optical fibres, homogeneous illumination is assured, together with high intensity of radiation of the mould cavity. By attaching a number of optical fibres to an ultraviolet lamp, an ultraviolet lamp can be used to crosslink a number of casting moulds, whereupon a very high intensity of illumination can be attained in an efficient manner, enabling rapid polymerisation of the filled moulding material to take place.

Further details and advantages of the invention may be seen from the description that follows and the drawing. In the drawing,

Fig.1 shows a schematic illustration of an embodiment of a UV illuminating device according to the invention;

Fig.2 shows a schematic illustration of a means of coupling the UV light into an optical fibre;

Fig. 3 shows a schematic illustration of the exposure of a casting mould by an optical fibre.

The UV illuminating device 1 illustrated schematically in fig. 1 is preferably mounted in a housing 16 illustrated only schematically here, and consists of a UV lamp 2 and several, advantageously 5 to 50, preferably 10 to 30 optical fibres 3, which surround the UV lamp 2 and are each fixed by a holder 4. The UV lamp 2 in question is suitably a mercury lamp, especially a doped medium pressure mercury lamp, whereby a medium pressure lamp HPA 2020 from Philips or a comparable medium pressure lamp from the company Heraeus can be used for example. The optical fibres 3 conveniently have a length of 0.3 to 2 m and are advantageously formed as liquid optical fibres, since these are particularly well suited to the transmission of UV light. Liquid optical fibres are notable for their high UV transmission, their more homogeneous distribution of intensity of the emerging light rays compared with quartz fibre bundles, and their higher usable cross-sectional area given the same diameter. The UV lamp 2 can be suitably mounted on a quick-change cradle (not illustrated) to enable the lamp 2 to be exchanged easily. The emission spectrum of the UV lamp 2 advantageously has a high UV intensity in the wavelength range 280 - 360 nm, since in this range various types of

photoinitiators that can be used in lens material can be activated, for example Irgacure 2050. Due in particular to the radial arrangement of the optical fibres 3 in relation to the longitudinal axis of the UV lamp 2, a high proportion of the radiation emitting from the UV lamp 2 can be coupled into the optical fibres 3 and thus used for crosslinking. The maximum number of optical fibres that can be used is dependent on the diameter of the UV lamp 2 and the distance to the UV lamp. In addition, there is advantageously a sensor 5, which measures the intensity of UV radiation. It is located near to the UV lamp 2. The measurement is passed on to a regulating unit 6 which compares the measured intensity of radiation with a theoretical value and regulates the current intensity I to keep it constant. In addition, a cool stream of air 7 is provided to cool the UV lamp 2. It is passed from the cold components over the hot components by means of an appropriate construction of the housing 16, or by a ventilator 22, respectively. The air stream is controlled by one or more temperature sensors 8 which measure the temperature inside the housing. The cool air stream ensures that the UV lamp 2 burns at an optimum temperature and that the components in the housing of the lamp do not become overheated. In this way, constant operating conditions are assured, which also prolong the life of the UV lamp 2.

The coupling of UV light into the optical fibres 3 is illustrated in more detail in fig. 2. In order to couple a high intensity of radiation into the optical fibres, a minimum distance to the UV lamp is required, advantageously ca. 1 mm. Since the surface of the UV lamp reaches a temperature or more than 800°C, direct coupling to a liquid optical fibre is impossible owing to its temperature sensitivity. Therefore, the light emitting from the UV lamp is firstly coupled into a quartz rod 9, the diameter of which is co-ordinated with that of the optical fibre 3. The length of the quartz rod 9 depends on the effectiveness of cooling produced by the stream of air. In a first approximation, the length of the quartz rod 9 has no affect on the light intensity that can be coupled into the optical fibres 3. Depending on the design of the lamp, the length of the quartz rod 9 is advantageously between 50 and 120 mm. Between the end of the quartz rod 9 facing away from the UV lamp 2 and the admission area 30 to the optical fibres, there is advantageously a cut-on filter 10 which shades out the short-waved UV radiation < 280 nm, since this causes a more rapid ageing of the optical fibres 3. The cut-on filter additionally prevents polymer degradation of the lens material. The cut-on filter 10 is suitably a WG 305 or 295 filter from the company Schott. Furthermore, a diaphragm 11 is provided between the cut-on filter 10 and the optical fibre admission area 30. By adjusting the aperture 12 of the diaphragm 11, the intensity of radiation entering the optical fibre 3 can be regulated. To regulate the coupled light intensity, the distance between the optical fibre

admission area 30 and the quartz rod 9 can also be modified. If a high UV intensity is desired, the distance should be as short as possible. In particular, there may be provisions for the diaphragm aperture 12 to be controlled via a stepping motor unit 13 which is linked to the diaphragm 11 in particular by a flexible coupling 14, whereby adjustment of the diaphragm aperture 12 can be regulated by the measurement of light intensity using a suitable UV measuring unit 15 at the light exit. There should be provision in particular for the diaphragm 11 of each optical fibre 3 to be adjustable independently. As well as solving this by means of a stepping motor unit, the diaphragms 11 may also be controlled manually if desired. The optical fibres 3 emerge from the housing 16 and are respectively arranged over a casting mould 17.

Fig. 3 depicts the exposure of a casting mould 17 consisting of a lower mould half 18 and an upper mould half 19. Arranged between the end of an optical fibre 3 and the upper mould half 19 is preferably a UV condenser 20, which consists of tempered quartz lenses. The condenser 20 serves to bundle the emitting ray of light. The optics thereof are co-ordinated with the geometry of the casting mould. In order to produce a contact lens which is polymerised throughout and has good quality of the edges, the distances between the end of the optical fibre 3 and the condenser 20 and between the condenser 20 and the upper mould half 19 are crucial. In addition, for an optimum path of rays, a diaphragm must be provided in the upper mould half 19. If the distance between the condenser 20 and the casting mould 17 is increased, the intensity of radiation is reduced. This leads to slower polymerisation of the lens material. However, if there is constant exposure time and the intensity of radiation is too high, the contact lenses become brittle and the quality of the edges of the contact lenses deteriorates. When selecting the distance between the condenser 20 and the upper mould 19, an optimum setting must be found, which also depends on the geometry of the upper mould half. This distance is suitably between 30 and 5 mm.

In this way, by coupling the UV light into the mould cavity using optical fibres, the invention enables the mould cavity to be illuminated evenly. By coupling a number of optical fibres to a UV lamp, a very high and even intensity of illumination can be attained in an efficient manner, so that it is possible to polymerise the introduced moulding material very rapidly.